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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,134	10/31/2000	Andrey A. Boukharov	04983.0201.00US00/38-21(5	8935

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/702,134	BOUKHAROV ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to the Amendment and Response filed November 12, 2003. Claims 1-4 have been amended, claims 5-7 have been canceled, and claims 8-12 have been added. Upon further consideration, the claims are rejected on new grounds, as set forth below. Any objections/rejections not reiterated in this action have been withdrawn. **This action is NON-FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. It is again noted that the title of the invention is not descriptive of the elected subject matter (which is a nucleic acid molecule, but not a use thereof). A new title is required that is clearly indicative of the invention to which the claims are directed.

The response traverses the requirement for a new title on the grounds that "a plant genome sequence is described throughout the specification, including in the examples, where a plant genome sequence and uses thereof are described in detail." This argument is not persuasive. The claims under examination are drawn to a product, not to any uses of the claimed product. *MPEP* 606.01 states that a title "indicative of the invention to which the claims are directed" is required. Accordingly, the title should describe the claimed invention, not the content of the specification. Applicant is again requested to provide a title descriptive of the elected invention. (It is further noted that MPEP 606.01 states that "If a satisfactory title is not supplied by the applicant, the examiner may, at the time of allowance, change the title by examiner's amendment.")

Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

5. Claims 1-4 and 8-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility. It is noted that Applicant's amendments necessitated the inclusion of new claims 8-12 in this rejection.

The claimed subject matter is not supported by a specific, substantial, and credible asserted utility because the disclosed uses are generally applicable to broad classes of this subject matter. Further characterization of the claimed subject matter

would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The specification teaches that SEQ ID NO 7212 is one of a group of over 50,000 large genomic fragments obtained from rice (see entire specification). The specification asserts that a variety of uses are applicable to all of the disclosed sequences, including use of the various sequences in genomic mapping, gene identification and analysis, plant breeding, preparation of expression constructs, preparation of transgenic plants, screening for traits, and determination of polymorphisms and of associations between polymorphisms and traits (see entire specification, particularly, e.g., pages 1, 12, and 18). However, the uses asserted in the specification are general utilities and methods of further research that are applicable to virtually any genomic nucleic acid from any plant. For example, any plant nucleic acid could be employed in genomic mapping, and any plant nucleic acid could be analyzed from the presence of genes (which genes could further be subjected to analysis); such general methods do not constitute substantial uses that are specific to one or more of the molecules disclosed by applicant. Further, while such mapping and nucleic acid analysis might eventually result in the identification of, e.g., particular regulatory elements useful in recombinant expression methods or in preparation of transgenic plants, specific polymorphisms associated with specific traits, particular open reading frames encoding useful proteins, etc., such further research and experimentation on nucleic acids also constitutes a general utility, rather than a specific and substantial "real world" use. See *Brenner v.*

Manson, 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". A patent is therefore not a license to experiment with the objective of eventually identifying a specific and substantial use for a product or method. With regard to SEQ ID NO: 7212 in particular, while the specification discloses that the sequence has been examined for homologies with known genes (see, e.g., Table 1), the specification does not provide any evidence that applicants have, e.g., identified within SEQ ID NO: 7212 any particular polymorphisms associated with a trait or traits, identified any particular promoters or regulatory elements useful in methods of recombinant gene expression, determined that any of the putative open reading frames in the sequence actually encodes a protein having a specific use, etc. Accordingly, the claimed invention is not supported by a specific, substantial and credible asserted utility.

With regard to the possibility that there may exist a well-established utility for the claimed invention, it is noted that SEQ ID NO: 7212 is free of the prior art. A search of the prior art indicates that SEQ ID NO: 7212 does contain a region of significant homology with a known molecule, specifically, with a rice cDNA encoding gibberellin 20-oxidase (GENBANK Accession No. U50333, February, 1997). However, an alignment of this cDNA with SEQ ID NO: 7212 reveals (in addition to multiple mismatches) multiple frameshifts within the coding sequence of the cDNA; accordingly, the prior art indicates that SEQ ID NO: 7212 and the prior art cDNA do not in fact encode the same protein. Thus, the prior art does not provide any evidence of a well-established utility for SEQ ID NO: 7212.

With regard to the rejection of claims 1-4 for lack of utility in the Office action of August 12, 2003, the response traversed the rejection on the following grounds. Applicant argues that the claimed invention possess numerous utilities, including those cited by the examiner in the Office action of August 12, 2003 (which utilities were identified by the examiner as being general utilities and methods of further research), as well as "obtaining protein molecules, determining the presence and/or identity of polymorphisms, measuring the levels of an mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements, screening cDNA genomic libraries, obtaining nucleic acid homologs, detecting and characterizing gene expression, etc." The response further argues that the uses disclosed in the specification "are directly analogous to a microscope" which is useful "to identify and characterize the structure of biological tissues in a sample, cell, or organism," and urges therefore that "the presently disclosed sequences possess the requisite utility" under 35 U.S.C. 101. Applicant states that the examiner "suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose" as the claimed molecules. Applicant urges that "there is no requirement of exclusive utility in the patent law," and states that "such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose." The response argues that the claimed molecules meet the utility requirement because they "will identify a unique subset of related sequences" which is

"specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule."

Applicant's arguments have been thoroughly considered but are not persuasive. First, with regard to the list of utilities recited by Applicant at pages 19-20 of the Response, it is noted that these utilities, like the other asserted utilities noted by the examiner in the Office action of August 12, 2003, constitute general utilities and methods of further research that are applicable to virtually any genomic nucleic acid from any plant. With regard to Applicant's argument that the claimed nucleic acids may be used "to identify and characterize other nucleic acid molecules within a sample, cell or organism" in a manner analogous to a microscope, this argument is not persuasive. Like the other general utilities discussed above, such a general use (in "identifying and characterizing" other nucleic acids) is applicable to virtually any genomic nucleic acid. While it is true that a microscope may be employed in identifying and characterizing tissues, this is also true of numerous types of equipment found routinely in laboratories, including gel electrophoresis apparatus, thermocyclers, vacuum blotters, etc.; all of these items may be used in various ways to achieve the general objective of "identifying and characterizing" biological tissues. However, a microscope is known to function in a particular way that differentiates it from these other types of equipment, and has a use in specific aspects of identification and characterization of tissues (e.g., visualization of structures) that differs from the specific uses of other types of equipment that are also useful in "identifying and characterizing" tissues. Accordingly, in contrast to the molecules of the claims, a microscope is not merely a member of a large genus of items

for which specific functions have yet to be identified, but rather a well characterized piece of laboratory equipment with a specific and substantial use. Applicant has yet to identify such a specific and substantial use for SEQ ID NO: 7212. Regarding Applicant's statement that the examiner "suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose," it is noted that the examiner did not make such a statement, but rather suggested that uses that are generally applicable to any nucleic acid cannot be considered a specific and substantial use for a particular nucleic acid molecule. It is acknowledged that a variety of different types of golf clubs may be used to hit a golf ball. However, this use in performing a specific task (i.e., hitting a golf ball) differentiates golf clubs from other types of athletic equipment (for example, tennis racquets). However, the instant specification does not disclose a substantial use that is specific either to SEQ ID NO: 7212 or, e.g., a group of molecules including SEQ ID NO: 7212 that would differentiate it from, for example, SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, etc. Further, while it is acknowledged that SEQ ID NO: 7212 could be used to differentiate, e.g., complements of SEQ ID NO: 7212 from complements of SEQ ID NO: 1, complements of SEQ ID NO: 2, etc., such a use is not specific and substantial unless a specific and substantial use for the molecule being detected has been identified. It is again noted that research and experimentation on nucleic acids constitutes a general utility, rather than a specific and substantial "real world" use. See *Brenner v. Manson*, 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". A patent is

therefore not a license to experiment with the objective of eventually identifying a specific and substantial use for a product or method. Accordingly, Applicant's arguments are not persuasive.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-4 and 8-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

With regard to the rejection of claims 1-4 for lack of enablement in the Office action of August 12, 2003, the response traverses the rejection on the grounds that the rejection has been overcome by the "arguments regarding utility" set forth above in paragraph 5. Accordingly, the response to those arguments applies equally herein.

8. Additionally, claims 1-4 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the teachings of the specification and of the prior art do not enable one skilled in the art to use molecules having any "nucleic acid sequence of SEQ ID NO: 7212 or its complement" or molecules "capable of specifically hybridizing" to such molecules, or molecules that have between 90%-100% identity with SEQ ID NO: 7212.

Claim 1 as written is sufficiently broad so as to encompass any molecule "having a nucleic acid sequence of SEQ ID NO: 7212 or its complement" (i.e., any subsequence

of the recited sequences, rather than the full length molecules), while claims 2-4 encompass molecules "capable of specifically hybridizing" to such a molecule. As discussed below, it is not clear what is meant by the language "capable of specifically hybridizing;" however, it is apparent that this language may encompass numerous molecules that hybridize under conditions of "moderate stringency." Accordingly, the claims are not limited to, e.g., nucleic acids encoding a protein with a particular biological activity, but rather embrace numerous other molecules. Further, the claims as written encompass subsequences of any length of SEQ ID NO: 7212 or its complement, and further embrace flanking sequences of unspecified length and identity. Claims 8-12 encompass molecules that are 90%-100% identical to SEQ ID NO: 7212, and which also may be flanked by sequences of any length and identity. Thus, the claims as written encompass allelic and splice variants SEQ ID NO: 7212 and fragments thereof, naturally and non-naturally occurring mutants of these sequence, variants isolated from other organisms, etc. The specification has not disclosed a specific and substantial utility even for, e.g., a particular nucleic acid consisting of SEQ ID NO: 7212, and further does not teach a biological function for the large genus of molecules encompassed by the claims, or otherwise provided guidance with respect to how such molecules may be used in a utility meeting the requirements of 35 USC 101. Additionally, it is again noted that the prior art is silent with respect to SEQ ID NO: 7212. Accordingly, while one of skill in the art could conduct further experimentation aimed at, e.g., identifying a particular function for the molecules of the claims, such a function is

not presently known, and the outcome of such experimentation cannot be predicted. Thus, it would require undue experimentation to use the claimed invention.

9. Claims 1-4 and 8-12 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

It is first noted that nucleic acids consisting of SEQ ID NO: 7212 meet the written description requirements. However, none of the instant claims are limited to such a molecule. It is again noted that claim 1 as written encompasses any molecule "having a nucleic acid sequence of SEQ ID NO: 7212 or its complement" (i.e., any subsequence of the recited sequences, rather than the full length molecules), while claims 2-4 encompass molecules "capable of specifically hybridizing" to such a molecule. As discussed below, it is not clear what is meant by the language "capable of specifically hybridizing;" however, it is apparent that this language may encompass numerous molecules that hybridize under conditions of "moderate stringency." The claims do not require that the molecules encompassed thereby be, e.g., the same length as and an exact complement of SEQ ID NO: 7212. Accordingly, the claims are not limited to, e.g., nucleic acids sharing the same function as SEQ ID NO: 7212 or encoding a protein with a particular biological activity, but rather embrace numerous other molecules. Further,

the claims as written encompass subsequences of any length of SEQ ID NO: 7212 or its complement, and further embrace flanking sequences of unspecified length and identity. Claims 8-12 encompass molecules that are 90%-100% identical to SEQ ID NO: 7212, and which also may be flanked by sequences of any length and identity. Thus, the claims as written encompass allelic and splice variants SEQ ID NO: 7212 and fragments thereof, naturally and non-naturally occurring mutants of these sequence, variants isolated from other organisms, etc. However, the specification does not exemplify nucleic acids that "specifically hybridize" to SEQ ID NO: 7212, or that have 90-99% identity with SEQ ID NO: 7212. Further, the claims recite open transitional language ("having"; "comprising"), and therefore include, e.g., molecules that are 90-100% identical with SEQ ID NO: 7212 and which further include undefined flanking sequences. As a result, the claims read on additional variants, mutants, homologues, etc., that differ completely from SEQ ID NO: 7212 with respect to both structure and function.

Additionally, while the instant claims recite structural properties for the molecules encompassed thereby, the claims fail to define the claimed molecules in terms of their functional properties. As a result, the claims as written embrace molecules with biological functions different and distinct from any function possessed by SEQ ID NO: 7212 and any protein encoded thereby. The specification does not disclose or exemplify any of the molecules embraced by the claims having an activity or function that differs from that which may be possessed by SEQ ID NO: 7212. Further, the general teachings of the art do not provide guidance with respect to how any alterations

of SEQ ID NO: 7212 would affect its function, as the affects of alterations made in one nucleic acid molecule are not predictive of the affects of such changes in another, unrelated molecule. Thus, given the lack of any functional requirements in the claims, the single molecule exemplified in the specification (SEQ ID NO: 7212) is not representative of the broad genus of molecules embraced by the claims. While the written description requirement does not require Applicant to disclose every species embraced by a claimed genus, the description of a genus is achieved by the recitation of a representative number of molecules encompassed by the genus, which molecules are usually defined by sequence. *Regents of the University of California v. Eli Lilly,* 43 USPQ2d 1398-1412. In the instant case, the particular molecule disclosed by Applicants is not representative of the broad genus claimed, and the written description requirement has not been satisfied. See also the Guidelines for Examination of Patent Applications under the 35 USC 112, first paragraph, "Written Description" Requirement, 66 Fed.Reg. 1099 (January 5, 2001).

Claim Rejections - 35 USC § 112, second paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-4 are indefinite over the recitation of the limitation "capable of specifically hybridizing to." Capability is a latent characteristic, and it is not clear

whether the molecules of the claims do in fact "specifically hybridize" or whether they are merely "capable of" doing so under particular conditions, following modifications, etc. Further, it is not clear from the teachings of the specification or the art as to what types of hybridization would be considered "specific" within the context of the claimed invention. For example, while only a molecule that is completely complementary to SEQ ID NO: 7212 is truly specific for SEQ ID NO: 7212, the specification states at page 23 that "a nucleic acid of the present invention will specifically hybridize to one or more of the nucleic acid molecules set forth in SEQ ID NO: 1 through SEQ ID NO: 52202 or complements thereof under moderately stringent conditions, for example at about 2.0 x SSC and about 40°C." Thus, the language of the specification suggests that the language "specifically hybridizes" may encompass numerous molecules that are not in fact specific for the target molecules to which they hybridize. Accordingly, as one of skill in the art could not determine what is encompassed by the language "capable of specifically hybridizing to," the claims are vague and indefinite.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Diana B. Johannsen
Patent Examiner
March 18, 2004